

### **REMARKS**

This paper is responsive to the Office Action dated November 18, 2004. Applicants have amended claim 17 for reasons unrelated to patentability. Claims 1-4, 6-13, 16-22, 24-31, 33-37 and 39-40 are still pending.

Claims 17, 18, 35-37, 39 and 40 are allowed.

In the previous two Office Actions, the Examiner indicated that the subject matter of claims 1-4, 6-13, 16-22, 24-31 and 33-34 was allowable. At that time, the same prior art references now being applied by the Examiner to reject claims 1-4, 6-13, 16-22, 24-31 and 33-34 were known by the Examiner and used by the Examiner for other rejections.

It appears that the Examiner has changed his mind for some unexplained reason regarding the allowability of claims 1-4, 6-13, 16-22, 24-31 and 33-34 in view of the prior art of record. Specifically, in the current Office Action, the Examiner rejected claims 1-4, 6-13, 16, 19-22, 24-31 and 33-34 under 35 U.S.C. 103(a) as being unpatentable over Krueger et al. (U.S. Patent 5,772,625) in view of Kashmer et al. (U.S. 4,465,485).

Applicants respectfully traverse these rejections. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

The only independent claims currently at issue are independent claims 1 and 19. Claim 1 recites a drip chamber system for draining cerebral spinal fluid (CSF) from a brain comprising a tube; an outlet manifold in fluid communication with the tube, the outlet manifold having an outlet; an inlet manifold in fluid communication with the tube, the inlet manifold having an inlet and an outer surface, the inlet manifold having a vent, the inlet manifold having an inside surface, the vent having a filter made of a porous material wherein a pore size of the porous material ranges from greater than .45  $\mu\text{m}$  to about 5.0  $\mu\text{m}$  and wherein the vent has a surface area ranging from about 0.8  $\text{cm}^2$  to about 5.0  $\text{cm}^2$ ; a drainage bag; and a stopcock connecting the tube to the drainage bag through the outlet.

Independent claim 19 recites a drip chamber system for draining cerebral spinal fluid (CSF) from a brain comprising a tube; an outlet manifold in fluid communication with the tube, the outlet manifold having an outlet; an inlet manifold in fluid communication with the tube, the inlet manifold having an inlet and an outer surface, the inlet manifold having a vent, the inlet

manifold having an inside surface, the vent having a filter made of a porous material wherein the pore size of the porous material ranges from about .22  $\mu\text{m}$  to about 5.0  $\mu\text{m}$ , and wherein the vent has a surface area ranging from about .0.8  $\text{cm}^2$  to about 5.0  $\text{cm}^2$ ; a drainage bag; and a stopcock connecting the drip chamber to a drainage bag through the outlet.

Again, in two previous Office Actions, the Examiner allowed claims 1 and 19 over the Krueger and Kashmer references. However, the Examiner has now changed his position without explanation, and asserted that a person of ordinary skill in the art would have been motivated to substitute the porous filter described in Kashmer into the drip chamber system of Krueger to arrive at the invention recited in claims 1 and 19.

The problem with the Examiner's analysis, however, is that neither Krueger nor Kashmer discloses or suggests a vent having a having a surface area ranging from about 0.8  $\text{cm}^2$  to about 5.0  $\text{cm}^2$  and a pore size ranging from about .22  $\mu\text{m}$  to about 5.0  $\mu\text{m}$ , as required by claim 19, or a surface area ranging from about 0.8  $\text{cm}^2$  to about 5.0  $\text{cm}^2$  and a pore size from greater than .45  $\mu\text{m}$  to about 5.0  $\mu\text{m}$ , as required by claim 1.

In the Office Action, the Examiner even recognized that Krueger and Kashmer both lack any suggestion of the surface area dimensions recited in Applicants claims. However, the Examiner stated that this would have been an obvious design choice to a person of ordinary skill in the art since Applicants have not disclosed that the claimed surface area dimensions solve any stated problem in the art or provide any advantage. The Examiner argued that the invention would perform equally well with the surface area of a vent as disclosed in Kruger. The Examiner cited no prior art teaching to substantiate his assertion that the invention would perform equally well with the surface area of a vent as disclosed in Kruger.

The Examiner appears to have a misunderstanding of the legal requirements of an obviousness analysis under 35 U.S.C. 103. If the prior art lacks any suggestion of the surface area dimensions recited in Applicants' claims, which the Examiner acknowledged, then the claims should be allowed.

Whether or not the novel structure recited in Applicants' claims provides any advantages is not probative of obviousness. While such evidence may be useful to Applicants to rebut a prima facie case of obviousness by showing that Applicants' specification provides motivation that the prior art lacks, the absence of any cited advantages of the claimed structure is not

sufficient to remedy the lack of a prior art teaching of the structural features. Moreover, in the instant case, the Examiner has acknowledged that the prior art does not teach a vent having a surface area ranging from about 0.8 cm<sup>2</sup> to about 5.0 cm<sup>2</sup>, as required by claims 1 and 19, and has cited no additional teaching that would have suggested such features. For this reason, the Examiner has failed to meet the Patent Office's burden of proof in establishing a prima facie case of obviousness.

In addition, Applicants note that the novel structure recited in claims 1 and 19 does in fact provide certain advantages, contrary to the Examiner's statements in the Office Action. In particular, Applicants' specification indicates that the relative sizes of the pores and the surface areas are important variables relevant to the creation of adequate venting for the drip chamber system. See page 7, second full paragraph of Applicants' specification. In this passage, the relative pore size and surface areas recited in claim 19 are specifically identified as advantageous to ensure adequate venting. *Id.* Moreover, in general, Applicants' specification indicates that the larger the pore size, the smaller the surface area that is needed to allow adequate venting of air from the drip chamber through the vent. *Id.*

It is well established that the Examiner bears the burden of establishing a prima facie case of obviousness.<sup>1</sup> In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention.<sup>2</sup> A prima facie case of obviousness is established only when this burden is met.

The Court of Appeals for the Federal Circuit has specifically addressed the evidentiary standard required to uphold an obviousness rejection.<sup>3</sup> Specifically, the Federal Circuit stated: "[the] factual question of motivation is material to patentability, and (can) not be resolved on subjective belief and unknown authority."<sup>4</sup> This finding must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.<sup>5</sup> Deficiencies in the evidentiary record cannot be cured by general conclusions such as "general knowledge" or "common

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<sup>1</sup> *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

<sup>2</sup> *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).

<sup>3</sup> *In re Lee*, 61 USPQ2d 1430, (CAFC 2002).

<sup>4</sup> *Id.* at 1434.

<sup>5</sup> *Id.*

sense.”<sup>6</sup> Accordingly, the Examiner cannot rely on unsupported, conclusory statements to close holes in the evidentiary record.<sup>7</sup> Unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill in the art to implement a vent having a having a surface area ranging from about 0.8 cm<sup>2</sup> to about 5.0 cm<sup>2</sup>, as required by claims 1 and 19, these claims should be allowed.

The conclusion of obviousness advanced by the Examiner in the Office Action relies on an incorrect analysis, insofar as the Examiner appears to be stating that Applicants must show some advantages of the novel structure in order to prove patentability. Of course, this is not the standard for an obviousness determination. The Patent Office, and not the Applicants, have the burden of proof in establishing that it would have been obvious to a person with ordinary skill in the art to implement a vent having a having a surface area ranging from about 0.8 cm<sup>2</sup> to about 5.0 cm<sup>2</sup>, as required by claims 1 and 19. Pursuant to this burden of proof, the Examiner must identify concrete evidence that such a surface area is suggested by the prior art. In the instant case, however, the Examiner has acknowledged that the applied prior art lacks any teaching of this feature.

Moreover, to the extent that the Examiner may be asserting that the present claims relate to a “critical variable,” Applicants further note that the law is well settled that patentability can be based on a claimed variable when the variable is critical to achieving particular results. *See Hughes Tool Co. v. Dresser Industries, Inc.*, 816 F.2d. 1549 (CAFC 1987).

In the instant case, Applicants’ claims recite the relative pore size and surface areas specifically identified as advantageous to ensure adequate venting. Accordingly, the pending claims meet the criticality standard set fourth in *Hughes Tool Co.*.

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<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

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Amendment dated March 16, 2005  
Responsive to Office Action mailed November 18, 2004

For at least the reasons set fourth above, all claims in this application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims. Applicants do not acquiesce to any of the Examiner's rejections or characterizations of the prior art, and reserve the right to present additional arguments with respect to the independent or dependent claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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